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FEDERAL COMMUNICATIONS COMMISSION
OFFICE OF THE SECRETARY

September 16, 1999

Commission Secretary
Magalie Roman Salas, Office of Secretary
Federal Communications Commission
The Portals
445 12th St. SW, Room TW-A325
Washington D.C. 20054

Dear Ms. Salas:

MedStar Health is a regional not-for-profit health care system in the Baltimore-Washington metropolitan area that includes seven hospitals with multiple outpatient sites, three ambulatory surgical centers, a large physician organization with sixty five sites, four long term facilities, two retirement residences, and a full complement of home care and hospice services. The mission of MedStar Health is to serve the needs of our communities by providing high-quality, advanced health care services in a manner that is customer service driven and that revolves around the needs of our patients. With over 3,200 licensed beds in our system, we recognize the critical role that medical telemetry plays in serving our patient population and in achieving our goals.

MedStar Health is very appreciative of the Federal Communications Commission's attention to the critical safety factors surrounding medical telemetry. We recognize that the bandwidths available to medical telemetry under 47 CFR Part 15 and Part 90 is diminishing as a result of the refarming of private land mobile radio and the conversion to digital television services and the resulting influx of low powered television services. We appreciate the opportunity to comment on the NPRM ET Docket 99-255 Wireless Medical Telemetry Service. Please accept and review our comments contained in the attached document.

Sincerely,

Caroline Campbell
Director, Biomedical Engineering
Washington Hospital Center

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Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Amendment of Parts 2 and 95 of	)	**ET Docket No. 99-255**
the Commission's Rules to Create a	)	
Wireless Medical Telemetry Service	)	

COMMENTS OF THE AMERICAN HOSPITAL ASSOCIATION TASKFORCE ON MEDICAL TELEMETRY

The MedStar Health Corporation by its attorneys and pursuant to Section 1.415 of the Commission's Rules, hereby files its comments on the Notice of Proposed Rule Making, released July 16, 1999, FCC 99-182 ("Notice") in the above-captioned proceeding. By this Notice, the Commission proposes to amend Parts 2 and 95 of its Rules to allocate spectrum and to establish regulations for a new Wireless Medical Telemetry Service ("WMTS").

MedStar Health strongly supports the Commission's proposal to allocate spectrum to WMTS on a primary or co-primary basis so that life-critical medical telemetry devices may operate on a blanket licensed, interference-protected basis in the newly allocated bands. MedStar Health commends the Commission for acting expeditiously in initiating this rule making and taking other pro-active measures to protect against the repetition of potential life-threatening incidents of harmful interference caused to wireless medical telemetry equipment.[1]

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[1] As discussed in the Notice, the Commission has worked together with the Food and Drug Administration to help ensure that hospitals are notified before new digital television (DTV) stations come on the air to provide them with time to modify any medical telemetry equipment that operates on the same frequency. Notice at para. 9. The Commission also placed a freeze on the filing of certain applications for high power

The Commission appropriately is planning now for the long-term spectrum requirements for WMTS. The near-term spectrum requirements of wireless medical telemetry equipment, however, cannot be ignored. Any rules adopted to facilitate the transition to WMTS expressly should authorize the continued use of lawfully manufactured wireless medical telemetry equipment in the Part 15 and Part 90 bands in which such equipment currently operates.

I. THE PROPOSED ESTABLISHMENT OF A PART 95 WIRELESS MEDICAL TELEMETRY SERVICE WOULD SERVE THE PUBLIC INTEREST

The Commission currently accommodates the use of biomedical telemetry devices on an unlicensed basis in the 174-216 MHz (VHF TV channels 7-13) and 470-668 MHz (UHF TV Channels 14-46) bands under Part 15 of its rules and at higher power levels in the 450-470 MHz band on a licensed basis under Part 90. Part 15 permits operation of biomedical telemetry devices with field strengths of 200 mV/m, measured at three meters, while hospitals or health care institutions that already hold Part 90 licenses in the Private Land Mobile Radio (PLMR) services are permitted to operate medical radio telemetry devices in the 450-470 MHz band without additional specific authorization with output powers up to 20 mW (330 mV/m at three meters). Operation of biomedical telemetry devices in these bands is generally subject to the

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operation in the 450-470 MHz band that might interfere with existing users of wireless medical telemetry equipment. Id. at para 5.

condition that no interference may be caused to any other user, and all interference from any other lawful use of the band must be tolerated.

Because of the introduction of digital television stations ("DTV") into TV broadcasting bands, some channels that were once unused for TV broadcasting, and thus available for wireless medical telemetry equipment operations, may now be used for DTV or low-power television broadcasting.[2] Moreover, medical telemetry equipment operating on a secondary basis to private land mobile radio services under Part 90 of the Commission's rules potentially may be subject to increased interference due to the new channeling scheme adopted by the Commission for PLMR services. In initiating this proceeding, the Commission correctly recognized that this potential for increased interference to medical telemetry equipment must be addressed.

The reliable use of wireless medical telemetry equipment is essential for health care providers to provide high quality and cost-effective care to patients with acute and chronic health care needs. Wireless biomedical telemetry devices are used in hospitals to transmit waveforms and other physiological data from patient measurement devices to a nearby receiver's antenna. One of the main purposes of patient monitoring is early detection of life-threatening physiologic developments so that appropriate intervention can be rendered in a timely manner in support of recovery. Typical devices may monitor ECG, oxygen saturation, blood pressure or respiration.

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[2] Id. at paras 6-8.

The use of these devices offers patients mobility earlier in their recovery, as well as improved comfort while still being monitored for adverse symptoms. In addition, such devices allow more patients to be monitored by each health care worker, thus decreasing health care costs.

With 300 channels of telemetry currently in use at the Washington Hospital Center, MedStar Health is one of the largest users of medical telemetry nationwide. In this critical environment, it is imperative that the new WMTS be established promptly, using spectrum which is allocated to WMTS on a primary or co-primary, interference-protected basis. MedStar Health commends the Commission for proposing such an allocation and urges expedited completion of this proceeding.

The medical telemetry within MedStar Health are anticipated to grow very rapidly in the future. Recovering cardiac patients continue to represent the largest segment of patients being monitored by wireless telemetry, but more acute patients also are being monitored, as are the supplemental devices, *e.g.*, ventilators, infusion pumps, *etc.*, that support these patients. As the Commission correctly concluded, the use of such devices should be subject to protection from interference in a broad array of environments constituting health care facilities, including not merely in hospitals, but also in other establishments that offer services, facilities, and beds for use beyond 24 hours in rendering medical treatment, and in institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and

similar establishments, including governmental entities and agencies for their own medical activities.[3]

II. MEDSTAR HEALTH ENDORSES THE COMMISSION'S PROPOSAL TO ALLOCATE THE WIRELESS MEDICAL TELEMETRY SERVICE A MINIMUM OF 14 MHz OF SPECTRUM BUT PROVIDES A REVISED RECOMMENDATION OF SPLIT BANDS FOR THE UPPER BAND ALLOCATION

A. The Pending Spectrum Allocation Proposals.

In the Notice, the Commission analyzed the current uses of, and the expressed potential interests in, the frequency bands recommended by American Hospital Association (AHA) as well as the bands adjacent to the AHA recommended frequencies. Based on this analysis, the Commission proposed a minimum allocation of 14 MHz to WMTS but formulated two alternative options which it considered more suitable to protect WMTS from harmful interference.

FCC Proposed Option 1

608-614 MHz (Channel 37)
1395 -1400 MHz
1429 - 1432 MHz

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[3] Notice at para. 28.

The Commission proposed 1395-1400 MHz in its Option 1 as an alternative to the 1385-1390 MHz band recommended by AHA in order to increase the frequency separation from, and thereby reduce the risk of interference by, U.S.-government radars operating below 1385 MHz. The Commission proposed the 1429-1432 MHz band as an alternative to the 1432-1435 MHz band recommended by AHA but noted that the proposed band also was being investigated by the Little LEO satellite operators for potential use for satellite feeder downlinks and was additionally requested for potential use for Part 90 PLMR services.[4]

FCC Proposed Option 2

608-614 MHz (Channel 37)
1391 -1400 MHz

[4] Notice at para 22.

The Commission explained that its Option 2 would provide an additional 1 MHz of spectrum (a total of 15 MHz), although it recognized that the larger, contiguous upper band would be less useful for two-way WMTS communications than if the upper band allocation were split, as in Option 1.[5] The Commission noted that proposed Option 2 would resolve the potential conflict with Little LEO satellite downlinks in the 1429-1432 MHz band but would result in a 2 MHz overlap with a possible 1390-1393 MHz Little Leo satellite feeder uplink allocation and would also use parts of the frequency bands requested for future Part 90 PLMR services.

MedStar Health applauds the Commission for its thoughtful analysis seeking to balance competing requests for frequency allocations with the need to protect wireless medical telemetry equipment from harmful interference. The Commission's proposed two options each correctly acknowledge the long-term need of WMTS to an allocation of 14 MHz of bandwidth or greater. The Commission for the most part also has identified the factors that must be considered in formulating a final allocation to the WMTS.

MeedStar Health endorses the Commission's proposal to adopt AHA's initial recommendation to allocate 608-614 MHz to WMTS on a co-primary basis. This band has low background noise because it is reserved for radio astronomy use. Because this band currently also is authorized for medical telemetry under the Commission's Part 15 rules, multiple

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[5] Id. at para 23

component vendors already have experience building equipment for this band and could develop new devices for use of these frequencies quickly. MedStar Health cautions, however, that this 6 MHz allocation of lower band frequencies is not sufficient bandwidth by itself to support WMTS either in the short-term or the long-term. In the long-term, additional bandwidth is needed in all geographic locations. In the short-term, an allocation of spectrum in addition to 608-614 MHz is required for locations in the vicinity of radio astronomy "quiet zones" and where broadcasters' use of TV Channels 36 or 38 may interfere with WMTS use of Channel 37 frequencies.

MedStar Health strongly prefers non-contiguous (split) frequencies in order to facilitate two-way communications on WMTS devices. Future technological advances likely will enhance the need for reliable two-way WMTS operations. MedStar Health believes that it will be very difficult for low power WMTS devices to share spectrum on an interference-free basis with the potential allocation of 1429-1432 MHz for Little LEO downlink operations. The Little LEO satellite systems will radiate signals of sufficient power to communicate with sensitive feeder link receiver terminals. It is unlikely that Little LEO downlink signals radiating across the country successfully can be coordinated with low power WMTS devices. Therefore, MedStar Health prefers that FCC Proposed Option 1, but urges the Commission to consider an alternate band in replacement of 1429-1432 MHz.

III. MEDSTAR HEALTH SUPPORTS THE COMMISSION'S PROPOSED FREQUENCY COORDINATION AND EQUIPMENT REGISTRATION PROCEDURES BUT OPPOSES BLANKET AUTHORIZATION OF WMTS DEVICES FOR IN-HOME USE

MedStar Health supports the AHA recommended appointment of a frequency coordinator to maintain a database of all WMTS equipment in operation and to notify users of potential frequency conflicts. A database maintained by a frequency coordinator is essential if WMTS is to be "licenced-by-rule" rather than by individual applications for licenses. Without such a database, there would be no record of which frequencies are used by each health care facility and each device. Accordingly, AHA supports the Commission's proposal that all parties using WMTS equipment be required to coordinate their operating frequency and other technical operating parameters with a coordinator to be designated by the Commission.

Until the industry and whoever the Commission designates as WMTS frequency coordinator gain experience in the frequency coordination of this new service, equipment in the WMTS bands should not be authorized for in-home medical uses. In-home uses likely are to be transient, both in terms of geographic location and duration; and it is unclear how the frequency coordinator can ensure that its database does not become extensively and unreasonably cluttered from transient uses that soon become inactive. Other alternatives exist to allow in-home uses of wireless medical telemetry devices, including devices authorized under the currently effective Part 15 and Part 90 rules. Although MedStar Health recommends that an express prohibition against using WMTS equipment for in-home medical uses be incorporated into the rules, it suggests that the Commission expressly note its willingness to apply the rule flexibly. The Commission may want to prohibit in-home use conditionally, subject to its authority to grant waivers on a case-by-case basis on a showing that the requested use will serve the same function as WMTS devices operated by authorized health care providers in health care facilities. The

Commission also may want to express its willingness to reconsider the prohibition against in-home uses of WMTS devices after some experience in frequency coordination of this service and a showing that in-home uses would be consistent with the intended purposes of WMTS.

However, MedStar Health agrees with the Commission that requiring renewal of equipment registrations every five years would be unreasonably burdensome. Health care facilities have been deploying wireless medical telemetry devices for many years without the requirement of renewing equipment registrations. It would be costly for health care facilities to set up new procedures to track the registration renewal dates for all the various types of WMTS devices they may utilize, and the price to be paid for any oversight in this ministerial task — cancellation of the equipment registration for a device that continues to perform life-protecting functions successfully — is too high.

MedStar Health supports a requirement that health care facilities notify the WMTS frequency coordinator when their use of registered WMTS frequency devices are being permanently discontinued and is confident that most facilities will handle this responsibility conscientiously. MedStar Health recognizes, however, that WMTS users would be better off if the database potentially were subject to some degree of "clutter" by containing entries for devices that no longer are in service than if the database were automatically purged of devices that continue in useful operation due to an inadvertent failure of a health care facility to renew an equipment registration. For this reason, WMTS equipment registration should be effective until affirmatively removed by the heath care provider. In cases of potential interference between two

WMTS devices, a new prospective user simply will bear the burden of identifying whether the prior-in-time use still is in operation and, thus, will require coordination with a new device.

Additionally, MedStar Health supports opening access to the frequency coordination database to all interested parties without restriction. Open access may aid manufacturers and potential users to identify locations where certain devices no longer are being used and, therefore, responsibly can be deleted from the database. MedStar Health also supports the Commission proposal not to require manufacturers to provide certain technical information to end users as part of the Declaration of Conformity process. [6] MedStar Health agrees that manufacturers will provide this information as a routine matter, so that no requirement is necessary.

IV. THE COMMISSION SHOULD ADOPT THE OTHER SERVICE RULE RECOMMENDATIONS OF AHA

The Commission solicited comments on various other service rule proposals. MedStar Health provides the following recommendations.

A. Certain Transmissions Over WMTS Spectrum Should Be Prohibited

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[6] Notice at para. 39.

AHA initially recommended that all types of information flows should be permitted in WMTS, including voice, data, video and telecommand, on both a unidirectional and bidirectional basis.[7] The Commission, however, expressed concern over allowing voice and video transmission in the WMTS. The Commission noted that allowing voice transmission could encourage the use of WMTS as a form of wireless intercom, rather than for its intended purpose of transmitting vital patient data, while video transmissions could occupy a significant portion of the available WMTS spectrum.[8]

MedStar Health shares the Commission's concerns. It supports the proposal to prohibit video transmission as long as it is clarified that this prohibition does not extend to the transmission of waveform information. MedStar Health also would not oppose initially prohibiting voice transmissions on WMTS frequencies because currently it does not foresee a voice application that would be consistent with the intended purpose of WMTS. MedStar Health, however, does not want to foreclose the possibility that a voice device could be designed to fit reasonably within the defined WMTS parameters. The Commission, therefore, may want

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7 See Notice at para. 33.

8 Id.

to consider conditionally prohibiting voice transmissions except on a special showing that such transmissions are consistent with the intended purpose of transmitting vital patient data.

V. THE COMMISSION SHOULD ALLOW THE CONTINUED USE AND PRODUCTION OF WIRELESS MEDICAL TELEMETRY EQUIPMENT OPERATING IN THE PART 15 AND PART 90 BANDS BEYOND THE EXPIRATION OF WHATEVER TRANSITION PERIOD IT ADOPTS

The Commission recognized that a transition period is necessary before requiring new equipment to be capable of operating in whatever frequency bands are allocated to WMTS. In its April 15, 1998, report, AHA estimated that manufacturers will require approximately three to four years to develop and market devices for WMTS bands and recommended a four year transition period.

In the Notice, however, the Commission states that it believes that four years is a longer transition period than necessary.[9] The Commission proposes that, beginning two years from the effective date of final rules in this proceeding, all medical telemetry equipment authorized must operate in the new frequency bands.[10] The Commission further proposes that medical telemetry equipment that already is in operation in the DTV and PLMR bands as of that date may continue

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[9] Notice t para. 41.

[10] Notice at para. 41.

to be operated, but at the users' own risk.[11] MedStar Health is supportive of the Commission's proposed two-year transition period.

However, the Commission should clarify that only newly designed devices that are first subject to an equipment authorization after the second anniversary of a decision allocating new frequencies to WMTS must be capable of operating in the newly allocated spectrum. It also should be made clear that such newly designed devices also may be capable of operating in the currently authorized Part 15 or Part 90 frequencies, subject to the users' own risk.

The continued use of any device that was lawfully manufactured and in operation by the two-year transition deadline should be "grandfathered" permanently. Use of these existing devices should be authorized until the user decides that they no longer are in acceptable working order or until they are being operated in an area where they are subject to objectionable interference from other, primary, licensed users. The health care industry simply cannot afford to replace the myriad of existing wireless telemetry devices until they have outlived their usefulness.

The continued manufacture of any wireless telemetry device that was lawfully manufactured prior to the expiration of the transition period also should be grandfathered, even if the device lacks the capability of operating in the WMTS bands. Lawfully manufactured

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[11] Id.

telemetry devices which have proven themselves in the marketplace should not be required to be withdrawn from production. Moreover, devices lawfully operating under Parts 15 or 90 prior to the transition deadline which merely are being re-authorized to reflect minor modifications should not be considered "newly designed" and also should be grandfathered for continued manufacture and operation outside the WMTS bands.

In sum, the Commission should allow the marketplace, not regulatory mandates, to drive the transition of wireless telemetry devices to the new Part 95 frequencies. If users continue to demand medical telemetry equipment operating outside the Part 95 frequencies, even though such equipment enjoys no mandated interference protection, the Commission should not stand in the way of such marketplace forces. Moreover, the flexibility to continue use of devices capable of operating under either Part 15 or Part 90 frequencies will be required in those areas mentioned in Section II.B above where WMTS use of Channel 37 already is not available. Such flexibility also is imperative because the completion of the WMTS transition to upper band frequencies undoubtedly will take an extended period of time, especially if incumbent government users take all the time authorized by Congress (that is, through the end of the next decade) to migrate out of these upper bands.[12] In order to accommodate an orderly migration to and from the newly allocated WMTS spectrum, therefore, the health care industry will require continued access to devices lawfully using the currently effective Part 15 and Part 90 spectrum allocations.

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[12] See Notice at para. 18 ("government operations [in the 1390-1400 MHz band] will continue at 17 sites until the year 2009").

VII. CONCLUSION

For the foregoing reasons, the Commission should establish promptly a Wireless Medical Telemetry Service under Part 95 of its rules and adopt rules consistent with the views expressed herein.

Respectfully submitted,

MEDSTAR HEALTH CORPORATE

REPRESENTATIVE

September 16, 1999